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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/142,305	09/10/1999	KEIYA OZAWA	50026/012001	2019

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CLARK & ELBING LLP
101 FEDERAL STREET
BOSTON, MA 02110

EXAMINER	
SISSON, BRADLEY L	
ART UNIT	PAPER NUMBER
1634	

DATE MAILED: 12/02/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/142,305	OZAWA ET AL.	
	Examiner	Art Unit	
	Bradley L. Sisson	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 September 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3,4 and 18* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3,4 and 18* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Specification

1. The specification contains numerous bibliographic citations, yet it has not been found to contain any statement that the cited documents have been incorporated by reference. As set forth in *Advanced Display Systems Inc. v. Kent State University* (Fed. Cir. 2000) 54 USPQ2d at 1679:

> Incorporation by reference provides a method for integrating material from various documents into a host document--a patent or printed publication in an anticipation determination--by citing such material in a manner that makes it clear that the material is effectively part of the host document as if it were explicitly contained therein. *See General Elec. Co. v. Brenner*, 407 F.2d 1258, 1261-62, 159 USQP 335, 337 (D.C. Cir. 1968); *In re Lund*, 376 F.2d 982, 989, 153 USPQ 625, 631 (CCPA 1967). **To incorporate material by reference, the host document must identify with detailed particularity what specific material it incorporates and clearly indicate where that material is found in the various documents.** *See In re Seversky*, 474 F.2d 671, 674, 177 USPQ 144, 146 (CCPA 1973) (providing that incorporation by reference requires a statement "clearly identifying the subject matter which is incorporated and where it is to be found"); *In re Saunders*, 444 F.2d 599, 602-02, 170 USPQ 213, 216-17 (CPA 1971) (reasoning that a rejection or anticipation is appropriate only if one reference "expressly incorporates a particular part" of another reference); *National Latex Prods. Co. v. Sun Rubber Co.*, 274 F.2d 224, 230, 123 USPQ 279, 283 (6th Cir. 1959) (requiring a specific reference to material in an earlier application in order to have that material considered a part of a later application); *cf. Lund*, 376 F.2d at 989, 13 USPQ at 631 (holding that **a one sentence reference to an abandoned application is not sufficient to incorporate from the abandoned application into a new application**). (Emphasis added.)

Attention is also directed to MPEP 608.01(p)I, which, in pertinent part, is reproduced below:

> Mere reference to another application, patent, or publication is not an incorporation of anything therein into the application containing such reference for the purpose of the disclosure required by 35 U.S.C. 112, first paragraph. In re de Seversky, 474 F.2d 671, 177 USPQ 144 (CCPA 1973). In addition to other requirements for an application, the referencing application should include an identification of the referenced patent, application, or publication. Particular attention should be directed to specific portions of the referenced document where the subject matter being incorporated may be found. (Emphasis added)

Accordingly, the cited documents are not considered to have been incorporated by reference and as such, have not been considered with any effect towards their fulfilling, either in part or in whole, the enablement, written description, or best mode requirements of 35 USC 112, first paragraph.

Claim Objections

2. Claims 1 and 18 are objected to because of the following informalities: The claims recite the term G-CSF" without setting forth the corresponding definition (i.e., granulocyte colony stimulating factor). Appropriate correction is required.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 3, 4, and 18 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Attention is directed to the decision in *University of Rochester v. G.D. Searle & Co.* 68 USPQ2D 1424 (Fed. Cir. 2004) at 1428:

> To satisfy the written-description requirement, the specification must describe every element of the claimed invention in sufficient detail so that one of ordinary skill in the art would recognize that the inventor possessed the claimed invention at the time of filing. Vas-Cath, 935 F.3d at 1563; see also Lockwood v. American Airlines, Inc., 107

> F.3d 1565, 1572 [41 USPQ2d 1961] (Fed. Cir. 1997) (patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that "the inventor invented the claimed invention"); In re Gosteli, 872 F.2d 1008, 1012 [10 USPQ2d 1614] (Fed. Cir. 1989) ("the description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed"). Thus, an applicant complies with the written-description requirement "by describing the invention, with all its claimed limitations, not that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." Lockwood, 107 F.3d at 1572.

4. For convenience, claim 1, the sole independent claim currently pending, is reproduced below.

1. (Currently Amended) A fusion protein comprising (a) a first polypeptide and (b) a second polypeptide, wherein said first polypeptide comprises a ligand binding domain of a steroid hormone receptor that, upon ligand binding, self-associates, and wherein said second polypeptide comprises a ~~cytokine~~ G-CSF-receptor or a ~~part~~ proliferation inducing domain thereof that, upon self-association of said first polypeptide, imparts proliferation activity to a cell.

5. For purposes of examination claim 1 has been construed as encompassing a very broad genus of fusion proteins wherein the "first polypeptide" of aid fusion protein that encompasses virtually any and all manner of "ligand binding domain of [any] steroid hormone receptor that, upon ligand binding, self-associates." The second polypeptide of the fusion protein has been interpreted as encompassing virtually any granulocyte colony stimulating factor receptor, or "proliferation inducing domain thereof that, upon self-association of said first polypeptide, imparts proliferation activity to [any] cell."

6. The written description requirement for a claimed genus may be satisfied by sufficient description of a representative number of species by actual reduction to practice, reduction to drawings or by disclosure relevant identifying characteristics, i.e. structure or other physical and/or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure or by a combination of such identifying characteristics sufficient to show applicant was in possession of the claimed genus. Furthermore, the Guidelines for Written Description state (hereinafter Guidelines):

> "The claimed invention as a whole may not be adequately described if the claims require an essential or critical feature which is not adequately described in the specification and which is not conventional in the art" (Federal Register/ Vol. 66, No. 4/Friday, January 5, 2001/Notices, column 1 page 1105). The Guidelines further state, "the claim as a whole, including all limitations found in the preamble, the transitional phrase, and the body of the claim, must be sufficiently supported to satisfy the written description requirement" (at page 1105, center column, third full paragraph). An applicant shows possession of the claimed invention by describing the claimed invention with all of its limitations. *Lockwood v. American Airlines Inc.* (CA FC) 41 USPQ2d 1 961 (at 1966).

7. A review of the application papers finds that no computer-readable Sequence Listing has been filed in the instant application.

8. A review of the disclosure finds the following six examples:

- Example 1, page 9, "Constructing the chimeric G-CSF receptor/estrogen receptor gene (a selective amplification gene).
- Example 2, pages 9-11, "Isolation of Ba/F3 cells into which was introduced the chimeric G-CSF receptor/estrogen receptor gene, which is a selective amplification gene."
- Example 3, page 11, "Analysis of cell proliferation by estradiol."
- Example 4, pages 11-12, "Construction of IRES-CD24 expression plasmid."
- Example 5, pages 12-13, "Intracellular expression of CD24."

- Example 6, pages 13-15, "Progenitor assays.'

9. The specification has not been found to provide an adequate written description of any amino acid sequence that is associated with any of the stipulated functions or activities of the various components.

10. It is noted with particularity that the invention of claims 1, 3, 4 and 18 is that of fusion proteins, a product, and not to methods for their production or to encoding constructs that can be used. A review of the disclosure fails to find a written description that describes the genus of fusion proteins both in terms of structure and function. As presently worded, the components of the fusion protein are identified by name and function, yet the amino acid sequences that are to be associated with such names and functionality are not provided.

11. None of the examples teach that any fusion protein has been produced and isolated and subsequently found to have the requisite activity, yet such embodiments are encompassed by the claims.

12. The specification does not provide sufficient description for a representative number of structural properties coupled with a known or disclosed structure to function correlation. The specification provides an example of Ba/F3 or murine mononuclear cells transformed with three variants of one type of cytokine receptor proliferation domain (i.e., murine G-CSF receptor). More particularly, two relevant fusion constructs are disclosed comprising a chimeric G-CSF receptor/estrogen ligand binding domain construct - "GCRER" as well as a construct with portions deleted in the G-CSFR extracellular domain from the 5th to the 195th residue - GCRΔ (5-l95)/ER. (e.g., p. 9, Example 1). Therefore, GCRA (5-195)/ER and GCRER are the only relevant embodiments that are disclosed.

13. In sum, two embodiments of a cytokine receptor are disclosed and one embodiment for a hormone ligand-binding domain (HBD), linked to either the wild type G-CSFR or GCRΔ (5-195).

14. The knowledge in the art does not provide sufficient relevant information to fill the gap present in the instant disclosure. For example, there are a few examples of particular fusion molecules consisting of a cytokine receptor and a hormone ligand-binding domain, whereby the fusion protein imparts cell proliferation. (e.g., Capon et al. US 5,837,544,. teach a chimeric constructs encoding a ligand-binding domain or an inducer-responsive clustering domain (ICD) linked to a proliferation signaling domain (PSD); Nakabeppu et al., Mol. Cell. Biol. 1993,. 13:4157-66,. teach a fusion protein comprising the *FosB* cytokine receptor domain linked to the human estrogen receptor ligand binding domain, whereby *FosB* regulated proliferation of quiescent cells). However, a handful of examples do not suffice to describe the genus of fusion molecule structures encompassed by the claims, wherein said structures correlate to cell proliferation.

15. The fusion molecule components (i.e., cytokine receptor domains and hormone ligand binding domains) are the essential element of the invention, but are not shown to be necessarily interchangeable, so that any combination will not necessarily result in the function of imparting cell proliferation. Such fusion constructs are not deemed to be "conventional" in the art, in the context of cell proliferation. (Supra, Guidelines, discussing critical or essential features of a claimed genus and the relative need for description when a feature is conventional in the art.)

16. In sum, given the enormous breadth of the genus of fusion molecules encompassed by the rejected claims, and given the limited description from the instant specification of such fusion

molecules, the skilled artisan would not have been able to envision a sufficient number of specific embodiments to describe the broadly claimed genus. Moreover, an applicant claiming a biotechnological invention cannot necessarily claim a genus after only describing a limited number of species because there may be unpredictability in the results obtained from other species (i.e., different combinations of receptors/binding domains comprising a given fusion molecule). Therefore, the skilled artisan would reasonably have concluded that applicants were not in possession of the claimed invention.

17. For the above reasons, and in the absence of convincing g evidence to the contrary, the rejection is maintained.

Response to argument

18. At page 7, bridging to page 8 of the response received 26 September 2005, hereinafter the response, argument is advanced that a similar rejection was withdrawn in a co-pending application and for the sake of uniformity of examination practice, the rejection in the instant application should also be withdrawn.

19. This argument has not been found persuasive as each application is considered on its own merits. It is further noted that consistency of prosecution does exist between this application and divisional application 09/905,92 as the claims in that application have also been repeatedly rejected under 35 USC 112, first paragraph, as not being adequately described by the specification.

20. At pages 8 to 13 of the response argument is advanced that the instant fact pattern is analogous to that of the instant application and therefore the rejection should be withdrawn.

21. The arguments contained therein have been fully considered and have not been found persuasive.

In the case of *Capon* is readily distinguished from the present application. As set forth in the decision of *Capon*,

> Both parties explain that their chimeric genes are produced by selecting and combining known heavy- and light-chain immune-related DNA segments, using known DNA-linking procedures. The specifications of both parties describe procedures for identifying and obtaining the desired immune-related DNA segments and linking them into the desired chimeric genes. Both parties point to their specific examples of chimeric DNA prepared using identified known procedures, along with citation to the scientific literature as to every step of the preparative method.
> The parties presented expert witnesses who placed the invention in the context of prior knowledge and explained how the descriptive text would be understood by persons of skill in the field of the invention. The witnesses explained that the principle of forming chimeric genes from selected segments of DNA was known, as well as their methods of identifying, selecting, and combining the desired segments of DNA.

22. By comparison, in the present case, no evidence has been presented that the genus of first polypeptides is well known in the art, and that the desired activity of the first polypeptide would be retained when coupled to the second polypeptide, even after binding ligand and self-assembly. Also, there is no evidence of record that the "proliferation domain" of any and all G-CSF were known. While non-patent documents have been submitted which speak to the general analysis of G-CSF, there is no evidence of record which points to the reproducible and predictable activity of a "proliferation-inducing domain" that would be effective in any and all manner of cells.

23. Unlike *Capon*, where expert testimony was presented, no such presentation is made here.

24. While applicant's representative has sought to underpin their argument by reliance upon publications, such showings do not take the place of sworn (declarations/affidavits) evidence and from which assurances that any statements or representations made are correct, as provided by

35 U.S.C. 25 and 18 USC 1001. *Ex parte Gray* 10 USPQ2d 1922 at 1928 (BPAI 1989).

Accordingly, applicant's representative's argument is non-persuasive.

It is further noted that applicant's representative presents conclusory opinion as to what would be known, adequately described, and fully enabled by one of skill in the art. These arguments have been fully considered and have not been found persuasive. Attention is directed to MPEP 2145.

> Attorney argument is not evidence unless it is an admission, in which case, an examiner may use the admission in making a rejection. See MPEP § 2129 and § 2144.03 for a discussion of admissions as prior art.
> The arguments of counsel cannot take the place of evidence in the record. In re Schulze, 346 F.2d 600, 602, 145 USPQ 716, 718 (CCPA 1965); In re Geisler, 116 F.3d 1465, 43 USPQ2d 1362 (Fed. Cir. 1997) ("An assertion of what seems to follow from common experience is just attorney argument and not the kind of factual evidence that is required to rebut a prima facie case of obviousness."). See MPEP § 716.01(c) for examples of attorney statements which are not evidence and which must be supported by an appropriate affidavit or declaration.

25. For the above reasons, and in the absence of convincing evidence to the contrary, the rejection is maintained.

Claims 1, 3, 4, and 18 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. As set forth in *Enzo Biochem Inc., v. Calgene, Inc.* (CAFC, 1999) 52 USPQ2d at 1135, bridging to 1136:

> To be enabling, the specification of a patent must teach those skilled in the art how to make and use the full scope of the claimed invention without 'undue experimentation.' " *Genentech, Inc. v. Novo Nordisk, A/S*, 108 F.3d 1361, 1365, 42 USPQ2d 1001, 1004 (Fed. Cir. 1997) (quoting *In re Wright*, 999 F.2d 1557, 1561, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993)). Whether claims are sufficiently enabled by a disclosure in a specification is determined as of the date that the patent application was first filed, see *Hybritech, Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1384, 231 USPQ 81, 94 (Fed. Cir. 1986).... We have held that a patent specification complies with the statute

> even if a "reasonable" amount of routine experimentation is required in order to practice a claimed invention, but that such experimentation must not be "undue." See, *e.g.*, *Wands*, 858 F.2d at 736-37, 8 USPQ2d at 1404 ("Enablement is not precluded by the necessity for some experimentation . . . However, experimentation needed to practice the invention must not be undue experimentation. The key word is 'undue,' not 'experimentation.' ") (footnotes, citations, and internal quotation marks omitted). In *In re Wands*, we set forth a number of factors which a court may consider in determining whether a disclosure would require undue experimentation. These factors were set forth as follows: (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims. *Id.* at 737, 8 USPQ2d at 1404. We have also noted that all of the factors need not be reviewed when determining whether a disclosure is enabling. See *Amgen, Inc. v. Chugai Pharm. Co., Ltd.*, 927 F.2d 1200, 1213, 18 USPQ2d 1016, 1027 (Fed. Cir. 1991) (noting that the *Wands* factors "are illustrative, not mandatory. What is relevant depends on the facts.").

26. A review of the application papers finds that no computer-readable Sequence Listing has been filed in the instant application.

27. A review of the disclosure finds the following six examples:

- Example 1, page 9, "Constructing the chimeric G-CSF receptor/estrogen receptor gene (a selective amplification gene).
- Example 2, pages 9-11, "Isolation of Ba/F3 cells into which was introduced the chimeric G-CSF receptor/estrogen receptor gene, which is a selective amplification gene."
- Example 3, page 11, "Analysis of cell proliferation by estradiol."
- Example 4, pages 11-12, "Construction of IRES-CD24 expression plasmid."
- Example 5, pages 12-13, "Intracellular expression of CD24."
- Example 6, pages 13-15, "Progenitor assays.'

28. It is well settled that one cannot enable that which they do not yet possess. As presented above, the specification does not reasonably suggest that applicant was in possession of the

claimed invention at the time of filing. Accordingly, the same deficient specification does not now enable the *making and use* of the broad genus of fusion proteins now claimed.

29. While claim 1 has been narrowed to where the second polypeptide comprises a "proliferation inducing domain," the specification and supporting argument found in the response do not teach that all elements of the fusion protein were well know, that the properties requires of the components of the fusion protein will be retained and have the desired effect (induce cell proliferation) under any conditions.

30. The specification is essentially silent as to how the various species of fusion proteins are to be used. It is noted with particularity that no reaction conditions, dosages, therapy regimens, etc., are provided. The situation at hand is analogous to that in *Genentech v. Novo Nordisk A/S* 42 USPQ2d 1001. As set forth in the decision of the Court:

> " '[T]o be enabling, the specification of a patent must teach those skilled in the art how to make and use the full scope of the claimed invention without undue experimentation.' *In re Wright* 999 F.2d 1557, 1561, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993); *see also Amgen Inc. v. Chugai Pharms. Co.*, 927 F. 2d 1200, 1212, 18 USPQ2d 1016, 1026 (Fed Cir. 1991); *In re Fisher*, 427 F. 2d 833, 166 USPQ 18, 24 (CCPA 1970) ('[T]he scope of the claims must bear a reasonable correlation to the scope of enablement provided by the specification to persons of ordinary skill in the art.').
>
> *****
>
> "Patent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable. *See Brenner v. Manson*, 383 U.S. 519, 536, 148 USPQ 689, 696 (1966) (starting, in context of the utility requirement, that 'a patent is not a hunting license. It is not a reward for the search, but compensation for its successful conclusion.') Tossing out the mere germ of an idea does not constitute enabling disclosure. While every aspect of a generic claim certainly need not have been carried out by an inventor, or exemplified in the specification, reasonable detail must be provided in order to enable members of the public to understand and carry out the invention.
> "It is true . . . that a specification need not disclose what is well known in the art. *See, e.g., Hybritech, Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1385,

> 231 USPQ 81, 94 (Fed. Cir. 1986). However, that general, oft-repeated statement is merely a rule of supplementation, not a substitute for a basic enabling disclosure. It means that the omission of minor details does not cause a specification to fail to meet the enablement requirement. However, when there is no disclosure of any specific starting material or any of the conditions under which a process can be carried out, undue experimentation is required; there is a failure to meet the enablement requirement that cannot be rectified by asserting that all the disclosure related to the process is within the skill of the art. It is the specification, not the knowledge of one skill in the art, that must supply the novel aspects of an invention in order to constitute adequate enablement. This specification provides only a starting point, a direction for further research. (Emphasis added)

31. Accordingly, and in the absence of convincing evidence to the contrary, claims 1, 3, 4 and 18 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement.

Response to argument

32. At page 13, bridging to page 14 of the response argument is presented in that the instant application is distinguishable over *Genentech* as "the present application not only provides ample description of the methods or making and using the fusion proteins at issue, but the invention was also reduced to practice a number of times." Attention is directed to Examples 1 and 4 "which are working examples that describe the construction of three selective amplification fusion genes of the present invention – GCRER, GCRΔ(5-195)/ER, GCRΔ(5-195, 725-726)/ER, alone and ligated with IRES-CD24.

33. The above argument ahs been fully considered and has not been found persuasive as at no time does said representative indicate where the specification fully enables the use of the claimed invention. The specification provides 6 examples:

- Example 1, page 9, "Constructing the chimeric G-CSF receptor/estrogen receptor gene (a selective amplification gene).
- Example 2, pages 9-11, "Isolation of Ba/F3 cells into which was introduced the chimeric G-CSF receptor/estrogen receptor gene, which is a selective amplification gene."
- Example 3, page 11, "Analysis of cell proliferation by estradiol."
- Example 4, pages 11-12, "Construction of IRES-CD24 expression plasmid."
- Example 5, pages 12-13, "Intracellular expression of CD24."
- Example 6, pages 13-15, "Progenitor assays.'

None of these examples are directed to the use of any one of the constructs in any method that would have utility. Additionally, the specification is essentially silent is showing that the components of the fusion protein would in fact have and retain the desired activities and functionalities when combined and used.

34. Absent such essential disclosure, the fact patter is deemed analogous, not non-analogous, to that of *Genentech.*

35. For the above reasons and in the absence of convincing evidence to the contrary, the rejection is maintained.

Conclusion

36. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

37. A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO

MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

38. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bradley L. Sisson whose telephone number is (571) 272-0751. The examiner can normally be reached on 6:30 a.m. to 5 p.m., Monday through Thursday.

39. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones can be reached on (571) 272-0745. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

40. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR

system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Bradley L. Sisson
Primary Examiner
Art Unit 1634

BLS
29 November 2005